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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,770	09/19/2003	Pankaj Jay Pasricha	D6475	6393

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,770	PASRICHA, PANKAJ JAY	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/27/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of **Group I, claims** drawn to a method for treating irritable bowel syndrome comprising administering a luminally active anti-inflammatory, and **beclomethasone** as a species of anti-inflammatory compound is acknowledged. Accordingly, claims 1-6 and 10-15 have been examined only to the extent of applicant's elected specie; and claims 7, 8, 9 and 16-18 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

2. Claims 10-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment of irritable bowel syndrome ... with pharmacologically effective amount", does not reasonably provide enablement for the "**inhibiting** the onset of symptoms of irritable bowel syndrome . . . . with a **prophylactically** effective amount". The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of **inhibiting** the onset of symptoms of irritable bowel syndrome or a related disorder in an individual in need of such treatment, comprising the step of: administering to the individual a **prophylactically** effective dose of a luminally active, beclomethasone. The nature of the invention is extremely complex in that it encompasses the actual inhibition of irritable bowel syndrome or a related disorder (i.e. any bowel disorder) such that the subject treated with above compounds does not contract irritable bowel syndrome or any related disorder.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass inhibition of a complex irritable bowel syndrome or a related disorder in humans which has no anatomic cause.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually **inhibit** irritable bowel syndrome or related disorders with **prophylactic** dose is minimal. All of the guidance provided by the specification is directed towards **treatment of irritable bowel syndrome with effective amounts** rather than **inhibition** with **prophylactic dose** with irritable bowel syndrome or **any related disorder.**

Working Examples: All of the working examples provided by the specification are directed toward the **treatment of irritable bowel syndrome with effective amounts** rather than **inhibition** with **prophylactic dose** with irritable bowel syndrome or **any related disorder.**

State of the Art: While the state of the art is relatively high with regard to treatment of **specific** bowel disorders (i.e. inflammatory bowel disease), the state of the art with regard to inhibition any disorder including irritable bowel syndrome and related bowel disorder is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to inhibit development of irritable bowel syndrome and related disorder. State of the art, Basu et al. (US 2002/0025348A1) report that **no single drug has proven to be effective** in the treatment of the **irritable bowel syndrome**. (page 2, left hand side lines 15-17).

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual inhibition of irritable bowel syndrome with

prophylactic dose in a human subject with the claimed compounds makes practicing the claimed invention unpredictable in terms of **inhibiting irritable bowel syndrome or related disorder with prophylactic dose.**

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for **inhibition of irritable bowel syndrome and related disorders with prophylactic dose**. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard inhibition of irritable bowel syndrome and related disorders comprising administering prophylactic dose with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding inhibition of irritable bowel syndrome and related disorders with prophylactic dose with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to inhibit the

development of irritable bowel syndrome or related disorders in a subject by administration of prophylactic dose of the claimed compounds.

Therefore, a method of inhibiting irritable bowel syndrome and related disorders in a subject administering prophylactic dose of beclomethasone is not considered to be enabled by the instant specification.

Written Description

Claims 1-6 and 10-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. Claims 1-6 and 10-15 are drawn to a method of treating or inhibiting irritable bowel syndrome or **a related disorder** comprising administering beclomethasone. The claims thus encompass a bread genus of **a related disorder** of irritable bowel syndrome.

The instant specification does not describe or exemplify all related disorder, much less a any symptoms and signs, lab findings, anatomical cause, demographic data of such related disorder qualified as a related disorder of irritable bowel syndrome. Accordingly, the instant specification does not provide a basis for one of skill in the art to envision the related disorders of irritable bowel syndrome. Given this lack of description of a sufficient number of diseases of the representative species encompasses by the

genus of the claim, the specification fails to described the claimed invention in such full, clear, concise, and exact terms regarding the related disorders of irritable bowel syndrome that a skilled artisan would not recognize that Applicants were in **possession** of the claimed invention, "a related disorder".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiesi et al. (WO 00/06132A2) evidenced by Basu et al. (U.S. 2002/0025348A1).

Chiesi et al. teach that pharmaceutical formulation for the treatment of inflammatory bowel disease containing as active ingredient beclomethasone dipropionate (BDP). (abstract). Chiesi et al. teach that the formulation demonstrate no systemic absorption of BDP and its major active metabolites. (page 14, Example 5). Chiesi et al. teach the amount of BDP to be employed includes 3mg and 5mg. (page 3, lines 9-11 and page 8-9 Examples 1 and 2).

Basu et al. report that **inflammatory bowel disease (IBD)** and **irritable bowel syndrome (IBS)** are related. (page 1, [0003]). Basu et al. report that IBS also tends to

occur in IBD patients who are in remission from their IBD symptomologies. (page 1, [0009], last full sentence).

Accordingly, Chiesi et al. teaches same individual having a related disorder of irritable bowel syndrome, inflammatory bowel disease, as evidenced by Basu et al. treated with same active agent comprising same effective dosages providing no systemic absorption of BDP as instantly claimed by the Applicant. Further, the mechanism of providing luminally active anti-inflammatory action of BDP by which the BDP gives the pharmacological effect of treating same disease condition (related disorder of irritable bowel syndrome, IBD) does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel the treatment of the conditions encompassed by the claims.

With regard to claim 10 drawn to "a method of **inhibiting** the onset of symptoms of **irritable bowel syndrome or a related disorder** in an **individual in need of such treatment**" is also anticipated by the prior art as evidenced by Basu et al. Basu et al. report that IBS tends to occur in IBD patients who are in remission from their IBD symptomologies. Therefore, the IBD patients disclosed by **Chiesi et al. are the patients in need of treatment of irritable bowel syndrome** because IBS tends to occur in IBD patients as taught by Basu et al. Further, claim 10 drawn to "inhibiting the onset of symptoms of irritable bowel syndrome" would be inherent in Chiesi's method of

treating inflammatory bowel disease comprising identical patient who is in need of treating irritable bowel syndrome as evidenced by Basu et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiesi et al. (WO 00/06132A2).

Chiesi et al. teach that pharmaceutical formulation for the treatment of inflammatory bowel disease containing as active ingredient beclomethasone dipropionate (BDP). (abstract). Chiesi et al. teach that the formulation demonstrate no systemic absorption of BDP and its major active metabolites. (page 14, Example 5).

Chiesi et al. teach the amount of BDP to be employed includes 3mg and 5mg. (page 3, lines 9-11 and page 8-9 Examples 1 and 2).

Chiesi et al. do not teach the specified amounts of beclomethasone set forth in claims 6 and 15.

It would have been obvious to one of ordinary skill in the art that the amount employed by Chiesi et al. (3mg or 5mg) for the treatment of inflammatory bowel disease (irritable bowel syndrome related disorder) is within the recited amounts set forth in claims 6 and 15 because Chiesi et al. teach same individual having same related disorder of irritable bowel syndrome comprising same effective dosages providing no systemic absorption of BDP as instantly claimed by the Applicant. Therefore, Chiesi et al. obviously administered same effective amounts within Applicant's recited amount in order to have same effect of treating inflammatory bowel disease which is related irritable bowel syndrome. It is noted that 5mg amount employed by Chiesi et al. is within the mg/kg recited in claims 6 and 15 when the subject to be treated weigh 50kg.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1617

Jmk
March 19, 2007